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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,866	04/16/2004	Michael A. Spohn	CV/04-001	8191
21140	7590	02/06/2008		
GREGORY L BRADLEY MEDRAD INC ONE MEDRAD DRIVE INDIANOLA, PA 15051			EXAMINER MACNEILL, ELIZABETH	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 02/06/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/825,866	SPOHN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Elizabeth R. MacNeill	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 December 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-21,23,25-49,83,85-98,116 and 117 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-21,23,25-49,83,85-98,116 and 117 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1,3-5,7-9,11,12,15,16,26-29,36,37,41-46,83,85-87,89-91,93,94,97, and 98 are rejected under 35 U.S.C. 102(b) as being anticipated by Duchon et al (US 6,099,502).

Duchon teaches an injector system comprising a source of injection fluid (50), a pump device (generally 20), a fluid path set (42) with a multiposition valve (26) disposed downstream of the pump (Fig 2c), and a valve actuator to automatically change the position of the multiposition valve (Col 9 lines 1-6). A position indicator is provided through display (58). The chamber open sensor (168) would indicate if the multiposition valve is missing, since the valve is in the chamber (Fig 19 at 554). An air detector is also provided (552) with closure members (627,628). The stop cock (34) acts as a shut-off valve. Hand-held control device (14) controls the flow rate of the injection. Fig 1 and Fig 19.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 6,10,17-20,30-35,40,88 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duchon in view of Sunderland (US 5,057,081).

Duchon teaches the limitations of claims 1 and 26, but does not teach a drip chamber.

Sunderland teaches a drip chamber for use in a peristaltic infusion device wherein the drip chamber (42) includes a body (48) with a longitudinally extending projection (50), an optical fluid level sensor (43), and a drip chamber support (39). The use of two drip chambers would be an obvious duplication of parts (*St Regis Paper Co v. Bemis Co.*, 193 USPQ 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the drip chamber and support of Sunderland in order to securely lock the drip chamber to the pump housing and ensure the drip chamber is in communication with the optical sensors. See Col 7-8.

5. Claims 13,14,38,39,95, and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duchon in view of Osborne et al (US 5,681,294).

Duchon teaches the limitations of claims 1 and 26, but does not teach a peristaltic pump or an automatic pinch valve. Osborne teaches a peristaltic fluid delivery system (52) with an automated pinch valve (80) (Col 15 lines 1-10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the peristaltic pump and/or automatic pinch valve of Osborne in order to improve the safety of the device and prevent free-flow of medicament to the patient.

6. Claims 21,23,25,47-49,116 and 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duchon in view of Gollinski et al (US 4,596,551).

Duchon teaches the limitations of claims 1 and 26, but does not teach that the retainers of the air detector are biased to the open position. Gollinski teaches a tube retainer which holds medical tubing in a secure position, wherein the retaining members are biased to the open position (Fig 4). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the tubing retainers of Gollinski to achieve the predictable result of providing a secure tubing retainer which is biased to be open.

### ***Response to Arguments***

7. Applicant's arguments with respect to claims 1,3-21,23,25-49,83,85-98,116 and 117 have been considered but not persuasive. Regarding Duchon, the valve 26 is expressly disclosed as automatic in Col 9 lines 1-6. Also, the valve may close the pump from the fluid line which would prevent (due to lack of pressure) delivery of fluid to the patient. Regarding Sunderland, the height of projection 50 extends longitudinally along the drip chamber and the annular rim 50 is designed to place the chamber in operational contact with the sensor. Applicant does not claim the projection is adjacent to sensors or that the sensor acts on the projection.

### ***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM



KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER

